Docket No. PHUS-7

REMARKS

Applicants acknowledge with much appreciation Examiner's efforts in handling examination of the present application and the courtesies extended during the recent telephone interviews concerning the above-identified application.

Claims 1-55 stand objected to since the earlier filed amendments did not comply with 37 C.F.R. 1.173 (b). Applicants now present the amended claims in a manner compliant with 37 C.F.R. 1.173 (b).

The claims **WERE PREVIOUSLY AMENDED** as follows:

In line 1 of ORIGINAL claim 1: deleted the term "improved".

In line 1 of subsection c) of ORIGINAL claim 1: replaced "or" with -- and/or --.

In line 1 of subsection c) of PREVIOUSLY ADDED claim 24: replaced "or" with -- and/or --.

In lines 2-5 of subsection d) of PREVIOUSLY ADDED claim 24: replaced the phrase "wherein the first ... one or more active agents" with -- wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents --.

In line 1 of subsection c) of PREVIOUSLY ADDED claim 25: replaced "or" with -- and/or --.

In lines 2-4 of subsection d) of PREVIOUSLY ADDED claim 25: replaced the phrase "wherein the first ... environments of use" with -- wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one

or more active agents --.

In line 1 of subsection c) of PREVIOUSLY ADDED claim 26: replaced "or" with -- and/or --.

In lines 2-4 of subsection d) of PREVIOUSLY ADDED claim 26: replaced the phrase "wherein the first ... environments of use" with -- wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents --.

In line 1 of subsection c) of PREVIOUSLY ADDED claim 27: replaced "or" with -- and/or --.

In lines 3-6 of subsection d) of PREVIOUSLY ADDED claim 27: replaced the phrase "wherein the first ... environments of use" with -- wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents --.

Applicants amended PREVIOUSLY ADDED claim 36 to include the subject matter of claim 25 and removed dependency from claims 26 and 27.

In line 2 of PREVIOUSLY ADDED claim 37: inserted -- and/ -- before "or".

In line 2 of PREVIOUSLY ADDED claim 40: inserted -- and/ -- before "or water".

PREVIOUSLY Added NEW claims 50-55 to cover the subject matter removed, by amendment of dependencies, from claim 36.

Applicants submit that no new subject matter was added by way of the amendment entered herein. The subject matter for the amendments is found in the issued patent (Col. 5, lines

1-57).

Applicants **NOW** further amend the claims as follows:

In line 1 of ORIGINAL claim 1: replace the term "An" with the term -- A --.

Applicants note that the status of claim 36, which depended from claim 25, 26 or 27 and which requires the presence of the PVP-VA polymer, was not indicated in the prior Office Action. Applicants assumed that the claim would be allowable if rewritten in independent form. Accordingly, claim 36 was therefore amended to include the subject matter of claim 25 and remove the dependency to claims 26 and 27. In addition, new claims 50-52 and 53-55 were presented to cover the subject matter of claim 36 in combination with claims 26, 37, 38 and claims 27, 37, 38, respectively.

Claims 1-23 PREVIOUSLY stood rejected under 35 U.S.C. §112, 2nd para. as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner indicated lack of clarity regarding the term "improved" in claim 1. Claims 2-23 depended either directly or indirectly from and include the subject matter of claim 1. Applicants amended claim 1 by deletion of the term "improved". Applicants respectfully submit that the rejection of claims 1-23 under 35 U.S.C. §112, 2nd para. was overcome and has been withdrawn.

Applicants note that claims 1, 24-27, 37 and 40 were also amended to include the term "and/or" in place of the term "or" in subsection c). Applicants submit that no new subject matter was added by way of amendment. As regards the external coat, the term "and/or" is clearly supported by the specification as originally filed and by the issued patent (Col. 5, lines 35-39).

Claims 24-35 and 37-49 PREVIOUSLY stood rejected under 35 U.S.C. §103(a) as being unpatentable over Savastano et al. (U.S. 5,681,584) [in view of] Herbig et al. (U.S. 5,609,590). Insofar as it may apply to the present claims, this rejection was respectfully traversed.

Applicants previously argued as follows. "Claims 24-27 are independent claims. Claims 28-49 depend directly or indirectly from those claims and include the subject matter thereof. In brief, claims 24-27 require a multi-layered osmotic device comprising a drug-containing core, a semipermeable membrane surrounding the core and having at least one preformed passageway there through, an inert, completely erodible and/or water soluble polymer coat surrounding the semipermeable membrane, and a drug-containing coat. As noted in the specification, the instant

osmotic device is capable of providing a range of different controlled release profiles. It does so even in the absence of any coating, e.g. the delayed release coating of Savastano et al., between the semipermeable membrane and the core. The instant device delivers drug substantially throughout the gastrointestinal (GI) tract (at least from the stomach and farther downstream thereof) by first delivering drug from the external coat and then delivering drug from the core of the device to the upper GI tract on down. By virtue of its design, the instant device is easier to manufacture and more versatile than that of Savastano et al. The present device does not require cooperation of two different coatings to provide controlled release of drug from the core.

"On the other hand, the device of Savastano et al. requires an additional delayed release jacket between the semipermeable membrane and the core even though Savastano et al.'s device already requires an external enteric coat. The internal delay jacket is required because the enteric coat does not sufficiently delay the release of drug from the core. In other words, the device of Savastano et al. requires cooperation of the delay jacket and the enteric coating in order to function as intended. Their device is adapted to deliver drug (from the core) to a particular region of the GI tract, in particular the lower end of the GI tract. Applicants submit that Savastano et al. would not be motivated to remove the delay jacket from their device, since its presence is required by virtue of it having to cooperate with the enteric coat (Col. 11, lines 30-31) to control release of drug from the core. Moreover, even in the absence of the enteric coat, the delay jacket continues to affect the rate of release of drug from the core (Col. 11, line 44 to Col. 12, line 5). Elimination of the delay jacket from the core would result in an osmotic device behaving differently than as intended by Savastano et al.

"The combination of the disclosures of Herbig et al. and Savastano et al. does not provide what Savastano et al. on its own is missing. Herbig et al. disclose bursting drug delivery devices. Their devices burst and provide a rapid release of drug after the internal osmotic pressure of the device has built up sufficiently to catastrophically rupture the membrane or seal of the device. Contrary to the instant device, the device of Herbig et al. does not provide a controlled release of drug from the core of the device while the membrane surrounding the core is physically intact. When properly combined in the absence of hind sight reconstruction, a prophetic osmotic device resulting from the proposed combination of disclosures would comprise: a core surrounded by a delay jacket that is then surrounded by an optionally rupturing semipermeable membrane, and then an enteric coating. The device would also include a pH sensitive coating external to the

semipermeable coating; however, its location with respect to the enteric coating could not be determined in view of the combined disclosures. The combination device may or may not provide a controlled release of drug, since the device of Herbig et al. includes a semipermeable membrane that ruptures but that of Savastano et al. does not. Moreover, the device might or might not provide an initial release of drug from an external drug-containing coat. The combination of Savastano et al. and Herbig et al. fails to disclose or suggest an osmotic device requiring all of the elements as claimed herein; therefore, the combination fails to render the claimed invention obvious."

"Accordingly, Applicants respectfully submit that the rejection of claims 24-35 and 37-49 under 35 U.S.C. §103(a) as being unpatentable over Savastano et al. (U.S. 5,681,584) [in view of] Herbig et al. (U.S. 5,609,590) was overcome and has been withdrawn."

Accordingly, Applicants submit that the objection to claims 1-55 has been overcome and request that is be withdrawn.

The previously filed oath/declaration was deemed to be defective for failing to identify the country of the priority application. Submitted herewith is a second supplemental declaration indicating the country of the priority application. Applicants respectvully submit that the oath/declaration is now compliant with 37 C.F.R. 1.175.

Applicants have made a diligent effort to advance the prosecution of the application by amending the claims, presenting supporting arguments, providing this amendment which now includes the amendments in a form compliant with 37 C.F.R. 1.173, and providing a corrected oath/declaration.

In view of the above, applicants submit that the claims are in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

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